

## IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A pharmaceutical gel preparation ~~including~~ comprising at least one pharmaceutically active ionic peptide compound mixed in a predetermined amount of the value  $X_{\text{optimum}}$  ~~[[()]]~~in mg of peptide per ml of the preparation~~[[()]]~~ with an aqueous solution of an inorganic or acetic acid salt in a predetermined concentration of the value  $Y_{\text{optimum}}$  ~~[[()]]~~in % weight/volume~~[[()]]~~, and after the mixing the administration can take place immediately, or a standing time of up to about 120 minutes, preferably between about 10 to about 120 minutes, particularly preferably between about 15 to 60 minutes is observed, and it being possible for the value  $X_{\text{optimum}}$  to be selected by a test method A including the stages of administration of various amounts where  $X_n$  is the ~~[[()]]~~number of different amounts  $n$ , where  $n \geq 1$ ~~[[()]]~~ ~~[[()]]~~in mg~~[[()]]~~ of the peptide as a mixture with an isotonic aqueous solution of mannitol onto or to a test system and selection of the amount  $X_{\text{optimum}}$  ~~[[()]]~~in mg of peptide per ml of mixture~~[[()]]~~ which provided in the experiment the most favorable blood plasma levels of the peptide in the test system in relation to  $C_{\text{max}}$  the ~~[[()]]~~maximum blood plasma concentration~~[[()]]~~ and  $t_{\text{max}}$  the ~~[[()]]~~time until  $C_{\text{max}}$  is reached~~[[()]]~~, and the concentration  $Y_{\text{optimum}}$  being selected by a test method B including the stages of administration of the amount  $X_{\text{optimum}}$  ~~[[()]]~~in mg of peptide per ml of mixture~~[[()]]~~ of the peptide as a mixture with aqueous solutions which differ in the concentration where  $Y_n$  is the ~~[[()]]~~number of different concentrations  $n$ , where  $n \geq 1$ ~~[[()]]~~ ~~[[()]]~~in % weight/volume~~[[()]]~~ onto or to a test system and selection of the concentration  $Y_{\text{optimum}}$  ~~[[()]]~~in % weight/volume~~[[()]]~~ was fixed as the concentration which in the experiment resulted in the highest value for the plasma concentration  $C_{\text{active}}$ , where  $C_{\text{min}} < C_{\text{active}} < C_{\text{max}}$  where ~~[[()]]~~ $C_{\text{min}}$  = lowest plasma concentration of the peptide at which the peptide still has an adequate pharmaceutical effect

in the experiment[[]]. At]] while at the same time, it has an influence on the time  $t_{\text{active}}$  until the highest concentration in the plasma is reached, where  $t_{\text{active}} > t_{\text{max}}$ .

Claim 2 (Currently Amended): The pharmaceutical preparation as claimed in claim 1, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is cationic.

Claim 3 (Currently Amended): The pharmaceutical preparation as claimed in claim 1, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is anionic.

Claim 4 (Currently Amended): The pharmaceutical preparation as claimed in claim 1, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is a mono-, di- or multi-valent cationic or anionic peptide.

Claim 5 (Currently Amended): The pharmaceutical preparation as claimed in claim 1, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is a mono-, di- or multi-valent ampholytic peptide.

Claim 6 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 5,~~ claim 1 wherein the pharmaceutically active ionic peptide compound has a length of from 5 to 20 amino acids.

Claim 7 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 5, characterized in that~~ claim 1 wherein the pharmaceutically active ionic peptide compound has a length of from 8 to 12 amino acids.

Claim 8 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 7, characterized in that~~ claim 1 wherein the pharmaceutically active ionic peptide compound is a GnRH analog.

Claim 9 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 7, characterized in that~~ claim 1 wherein the pharmaceutically active ionic peptide compound is a GnRH antagonist.

Claim 10 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 9, characterized in that~~ claim 1 wherein the pharmaceutically active ionic peptide compound ~~has been~~ is selected from the group consisting of cetrorelix, teverelix, abarelix, ganirelix, azaline B, antide, detirelix, ramorelix, degarelix, D-63153 or their pharmaceutically active salt ~~or~~ and mixtures thereof.

Claim 11 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of claims 1 to 10, characterized in that~~ claim 1 wherein the pharmaceutically active ionic peptide compound is the GnRH antagonist D-63153.

Claim 12 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the inorganic salt or the acetic acid salt is a physiologically tolerated salt.

Claim 13 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~  
~~of the aforementioned claims, characterized in that~~ claim 1 wherein the aqueous inorganic  
salt or acetic acid salt ~~has been~~ is selected from the group consisting of sodium chloride,  
calcium chloride, magnesium chloride, sodium acetate, calcium acetate, ~~and~~ magnesium  
acetate and mixtures thereof.

Claim 14 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~  
~~of the aforementioned claims, characterized in that~~ claim 1 wherein the mixture of the  
pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic  
salt or of the acetic acid salt is a liquid suspension or a semisolid dispersion.

Claim 15 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~  
~~of the aforementioned claims, characterized in that~~ claim 1 wherein the amount X of the  
pharmaceutically active ionic peptide compound is in the range from about 5 to about 50 mg  
per ml of the total amount of the pharmaceutical preparation.

Claim 16 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~  
~~of the aforementioned claims, characterized in that~~ claim 1 wherein the amount X of the  
pharmaceutically active ionic peptide compound is in the range from about 10 to about 50 mg  
per ml of the total amount of the pharmaceutical preparation.

Claim 17 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~  
~~of the aforementioned claims, characterized in that~~ claim 1 wherein the amount X of the

pharmaceutically active ionic peptide compound is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 18 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the amount X of the pharmaceutically active ionic peptide compound is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claim 19 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the amount X is in the range from about 5 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 20 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 19 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the amount X is in the range from about 10 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 21 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 19 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the amount X is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 22 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 19 wherein D-63153 is the

pharmaceutically active ionic peptide compound, and the amount X is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claim 23 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the concentration Y of the aqueous inorganic or acetic acid salt solution is equal to or less than 0.90 (weight/volume).

Claim 24 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the concentration Y of the aqueous inorganic or acetic acid salt solution is in the range from about 0.01% to about 0.9% (weight/volume).

Claim 25 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the concentration Y of the aqueous inorganic or acetic acid salt solution is in the range from about 0.05% to about 0.5% (weight/volume).

Claim 26 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the concentration Y of the aqueous inorganic or acetic acid salt solution is about 0.1% (weight/volume).

Claim 27 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the inorganic salt is

sodium chloride, and in that the concentration Y is equal to or less than about 0.9% (weight/volume).

Claim 28 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the inorganic salt is sodium chloride, and in that the concentration Y is in the range from 0.01% to about 0.9% (weight/volume).

Claim 29 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the inorganic salt is sodium chloride, and in that the concentration Y is in the range from 0.05% to about 0.5% (weight/volume).

Claim 30 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein the inorganic salt is sodium chloride, and in that the concentration Y is about 0.1% (weight/volume).

Claim 31 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein at least one of the pharmaceutically active ionic peptide compound is D-63153, and the inorganic salt is sodium chloride.

Claim 32 (Currently Amended): The pharmaceutical preparation as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 1 wherein at least one of the pharmaceutically active ionic peptide compound is D-63153, and the amount X thereof is



about 25 ml per ml of the preparation, and in that the inorganic salt is sodium chloride, and the concentration Y thereof is about 0.1% (weight/volume).

Claim 33 (Currently Amended): A method for producing a pharmaceutical preparation ~~including~~ comprising the steps A) bringing together an amount  $X_{\text{optimum}}$  [[~~( )~~]] in mg per ml of the finished preparation[[~~( )~~]] of at least one pharmaceutically active peptide compound in lyophilized form and an aqueous solution of an inorganic or acetic acid salt in a concentration with the value  $Y_{\text{optimum}}$  (% weight/volume) and A) B) mixing the components.

Claim 34 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is D-63153, and the inorganic salt is sodium chloride.

Claim 35 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, ~~characterized in that~~ wherein the pharmaceutically active ionic peptide compound is D-63153, and the amount thereof is about 25 mg/ml, and in that the inorganic salt is sodium chloride, and the concentration thereof is about 0.1% (weight/volume).

Claim 36 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 33, further comprising the step of sterilization of the peptide formulation by irradiation with gamma rays or electron beams takes place.



Claim 37 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 33, where the production of the peptide formulation takes place with use of aseptic procedures.

Claim 38 (Currently Amended): A kit for producing a pharmaceutical preparation, ~~including~~ comprising a previously fixed amount X ~~[[()]]~~ in mg per ml of the finished preparation~~[[()]]~~ of a pharmaceutically active ionic peptide compound in lyophilized form and of an aqueous solution of an inorganic or acetic acid salt in a previously fixed concentration Y % (weight/volume).

Claim 39 (Currently Amended): The kit as claimed in claim 36, ~~characterized in that~~ wherein the pharmaceutically active peptide compound is D-63153 in lyophilized form.

Claim 40 (Currently Amended): The kit as claimed in claim 36, ~~characterized in that~~ wherein the D-63153 lyophilizate additionally comprises mannitol.

Claim 41 (Currently Amended): The kit as claimed in claim 36, ~~characterized in that~~ wherein the inorganic salt is sodium chloride.

Claim 42 (Currently Amended): The kit as claimed in ~~any of the preceding claims,~~ claim 36 wherein the amount X of D-63153 is about 25 mg per finished preparation and the concentration of the aqueous sodium chloride solution is about 0.1% weight/volume.

Claim 43 (Currently Amended): A method for treating a patient with a pharmaceutically active peptide compound, ~~characterized in that~~ wherein a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 is administered subcutaneously or intramuscularly to the patient by means of a syringe.

Claim 44 (Currently Amended): The method as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity.

Claim 45 (Currently Amended): The method as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 4 weeks.

Claim 46 (Currently Amended): The method as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 8 weeks.

Claim 47 (Currently Amended): The method as claimed in ~~any of the aforementioned claims, characterized in that~~ claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 12 weeks.

Claim 48 (Currently Amended): A method for treating a hormone-dependent disorder in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 49 (Currently Amended): A method for treating prostate cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 50 (Currently Amended): A method for treating breast cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 51 (Currently Amended): A method for treating uterine myomas in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 52 (Currently Amended): A method for treating endometriosis in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 53 (Currently Amended): A method for treating precocious puberty in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 54 (Currently Amended): A method for modifying the reproductive function in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in ~~any of the aforementioned claims~~ claim 1 in a patient requiring this.

Claim 55 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~ ~~of the aforementioned claims~~ claim 1 wherein the mixture of the pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic salt or of the acetic acid salt is a molecular-dispersed or colloidal mixture which may be of liquid to semisolid consistency.

Claim 56 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~ ~~of the aforementioned claims~~ claim 1 wherein a colloidal dispersion is formed by reconstitution.

Claim 57 (Currently Amended): The pharmaceutical preparation as claimed in ~~any~~ ~~of the aforementioned claims~~ claim 1 wherein a colloidal dispersion is formed by storage or leaving to stand after reconstitution and changes its viscosity as a function of time and thus improves the reproducibility of the delayed release of active ingredient.

Claim 58 (Currently Amended): A kit comprising a lyophilized pharmaceutically active peptide, ~~for example D-63153, where appropriate~~ optionally together with one or more pharmaceutically acceptable excipients or additives, and a low-concentration aqueous solution of an inorganic salt, ~~preferably sodium chloride~~.

Claim 59 (New): The kit as claimed in claim 58, wherein the lyophilized pharmaceutically active peptide is D-63153.

Claim 60 (New): The kit as claimed in claim 58, wherein the inorganic salt is sodium chloride.